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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,402	ERIKA ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/22/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12,21-42,46,47 and 56-68* is/are pending in the application.

4a) Of the above claim(s) *32-42,46,47,56-66 and 68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-12, 21-31 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 06/22/2009 has been entered.

Status of Claims

2. Claims 1-10, 13-20, 43-45 and 48-55 are cancelled. Claim 68 is added. Claims 11-12, 21-42, 46-47 and 56-68 are pending. Claims 32-42, 46-47, 56-66 and 68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/18/2007. Claims 11-12, 21-31 and 67 are under examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 11-12, 21-22, 30-31 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vande-Velde.,[1] in view of Zanone et al.[2]

In response to the rejection, Applicant argues that Vande-Velde et al. does not teach an antacid that act protectively through the mucous membrane, such as sucralfate, which is cytoprotective.

Applicant's argument has been considered, however it is not persuasive. As acknowledged by the Office, while it is not readily apparent from teachings of Vande-Velde if any of the antacids disclosed in the reference acts protectively through the mucous membrane, however, to cure for the noted deficiency in Vande-Velde, the Office cited Zanone et al. and issued an obviousness rejection instead of an anticipatory rejection. In the instant case, Vande-Velde teaches a vaccine comprising an antigen and an antacid. And, at the time the invention was made, Zanone et al. teaches the use of sucralfate as an antacid. Sucralfate is an antacid that Applicant's disclosure notes to act protectively through the mucous membrane. Hence an obviousness rejection is issued over Vande-Velde in view of Zanone et al.

It is further noted that Applicant argues that one of skill in the art would not have been motivated from the teachings of Vande-Velde to use the elected species, sucralfate because sucralfate is not dissolvable at neutral pH, i.e., in saliva, as required by Vande-Velde because the antacids disclosed in Vande-Velde must be capable of dissolving in the oral cavity.

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[1] Vande-Velde, U.S. PreGrant Patent No. 20040013695.
[2] Zanone et al. U.S. Patent No. 6497859, filed 11/17/2000.

Applicant's argument has been considered, however, it is not found persuasive. While Applicant correctly notes that the vaccine composition of Vande-Velve, which comprises an antacid, is an oral composition, however, it is noted that Applicant misconstrued the teachings of Vande-Velve. As noted in the Vande-Velde disclosure, the prefer antacid is water-insoluble. [Paragraphs 0006 and 0033, in particular.] Water has a pH of 7, which is neutral. Thus, an antacid that is water-insoluble is not dissolvable at neutral pH, i.e., in saliva.

In addition to above, Applicant claims unexpected results. To support Applicant's argument, Applicant notes that claimed vaccine composition generates an improved immune response involving the production of immunoglobulins, a Th2 response that involves the generation of IgE. Applicant also notes that Vande-Velde does not teach or suggest that antacids can be used to stimulate Th2 response.

Applicant's argument has been considered, however, it is not found persuasive. MPEP 2112 states, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." In the instant case, the ability of sucralfate taught by Zanone et al. to induce a Th2 immune response is inherent of the antacid itself, as evidenced by Untersmayr et al.[3] The reference evidences that antacids, including sucralfate impair gastric digestion, which leads to the promotion of IgE, Th2 response.

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[3] Untersmayr et al. Antacid Medication Inhibits Digestion of Dietary Proteins and Causes Food Allergy A Fish Allergy Model in Balb/c Mice. *Journal of Allergy and Clinical Immunology*, Volume 112, Issue 3, Pages 616-623.

Directing arguments at Zanone et al., Applicant argues that the reference does not teach or suggest the use of antacids that are mucosally protective.

Applicant's argument has been considered, however, it is not found persuasive. The antacid that Zanone et al. teaches is sucralfate. Sucralfate is mucosally protective, as disclosed in Applicant's specification. In the instant case, Zanone et al. does not need to disclose that sucralfate is mucosally protective in order to render Applicant's claimed invention obvious for such is inherent of sucralfate itself.

Applicant also argues that Zanone et al. does not provide the motivation to sue a mucosally protective antacid.

Applicant's argument has been considered, however, it is not found persuasive. The rejection is over Vande-Velve in view of Zanone et al. In the instant case, Vande-Velve teaches the use of antacids with vaccines. While it is not readily apparent if the antacids disclosed by Vande-Velve include those that are mucosally protective, the Office introduces the teachings of Zanone et al. Had Vande-Velve readily teaches a mucosally protective antacid, then, the rejection would have been over Vande-Velve itself and not in view of Zanone et al. In the instant case, the motivation to use antacids is clearly detailed by Vande-Velve, and Zanone et al. provides a listing of antacids available for use with the vaccine composition of Vande-Velve, at the time the invention was made.

Additionally, Applicant asserts that the Office has improperly used hindsight.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the obviousness rejection clearly takes into account only the knowledge which was within the level of ordinary skill at the time the invention was made. Vande-Velve teaches a vaccine composition comprising an antigen and an antacid. And, Zanone et al. establishes that sucralfate is known in the art as an antacid, at the time the invention was made. Additionally, the rejection clearly does not include knowledge gleaned only from Applicant's disclosure. Therefore, contrary to Applicant's assertion, the rejection is proper.

The claims are directed to a vaccine composition comprising an antigenically active substance and a gastric acid reducing substance that is an antacid that act protectively through the mucous membrane. Claim 12, which depends on claim 11, requires the gastric acid reducing substance to increase the pH in the stomach to between pH 4 and pH 7. Claims 21-22, which depend on claims 11-12, respectively, require antigenically active substance to be one or more natural antigens, synthetic antigens, antigen mimotopes or a combination thereof. Claims 30-31, which depend on claims 11-12, limit the antigenically active substance be a tumor antigen.

It is noted that Applicant's specification identifies sucralfate and carbenoxolone as antacids act protectively through the mucous membrane.

Vande-Velde teaches a vaccine composition comprising an antigenically active substance and a gastric acid reducing substance. [Abstract, in particular.] The gastric acid reducing agent used by Vande-Velde is an antacid. The antigenically active substances that Vande-Velde teaches include natural and synthetic antigens and tumor antigens. [Claims, page 12, in particular.]

The antacid that Vande-Velde teaches includes aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate. It is not readily apparent from the teachings of Vande-Velde if any of the antacids disclosed in the reference acts protectively through the mucous membrane.

However, Zanone et al. teaches the use of sucralfate as an antacid, along with the other antacids disclosed by Vande-Velde, including aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate.

At the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use sucralfate as an antacid in the composition of Vande-Velde. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to make a vaccine composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of functional equivalents, one antacid for another, is routinely practiced in the art.

Regarding the limitation of claims 12, which requires the gastric acid reducing substance to increase the pH in the stomach to between pH 4 and pH 7, it should be noted that the vaccine composition of Vande-Velde does comprise at least one antacid.

The purpose of antacid is to reduce stomach acid level. In view of the known properties of antacids, the vaccine composition of Vande-Velde would have inherently reduced stomach/gastric acid levels, when administered. Hence, while Vande-Velde may be silent on the pH level in the stomach of subjects receiving his vaccine composition, the composition of Vande-Velde does comprise an antacid. Therefore, his vaccine composition would necessarily increase the pH level in the stomach of subjects receiving the vaccine composition. Additionally, Vande-Velde et al. teaches the use of large volumes of antacids to neutralize stomach acids to avoid antigenic degeneration caused by stomach acid. [Paragraphs 002 and 0006, in particular.]

5. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vande-Velde and Zanone et al., as applied to claims 11-12 and 21-22, in view of Martin et al.[4]

In response to the rejection, Applicant argues that the Martin et al. reference fails to remedy the insufficiency Applicant has noted in Vande-Velde and Zanone et al. in the primary obviousness rejection.

Applicant's argument has been considered, however, it is not found persuasive. The significance of Vande-Velve and Zanone et al., as applicable, is provided in paragraph no. 4 of this office action. Contrary to Applicant's assertion, Martin et al. remedies the deficiency of Vande-Velve and Zanone et al., as applied to claims 23-25.

[4] Martin et al. U.S. PreGrant Patent No: 20030049271, which has priority to U.S. Provisional No. 60/269841.

Claim 23, which depends on claim 21, requires the natural or synthetic antigen be coupled to a carrier. Claims 24-25, which depend on claims 22-23, respectively, require the natural or synthetic antigen be conjugated to a carrier.

The significance of Vande-Velde, as applied to claims 11-12 and 21-22, is provided above. While Vande-Velde does suggest the addition of a carrier with his vaccine composition, it is not readily apparent if Vande-Velde coupled and/or conjugated the natural or synthetic antigen to the carrier. [Paragraph 0035, in particular.]

However, at the time the invention was made, Martin et al. establishes that the coupling and conjugation of antigen to a carrier stimulates the development of a stronger immune response. [Paragraph 0100, in particular.] Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to couple and conjugate antigens to a carrier. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to stimulate the development of a stronger immune response. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because coupling and conjugation are routinely practiced in the art.

6. Claims 23 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vande-Velde and Zanone, as applied to claims 11-12 and 21-22, in view of Kricek et al.[5]

[5] Kricek et al. U.S. Patent No. 6610297.

In response to the rejection, Applicant argues that the Kricek et al. reference fails to remedy the insufficiency Applicant has noted in Vande-Velde and Zanone et al. in the primary obviousness rejection.

Applicant's argument has been considered, however, it is not found persuasive. The significance of Vande-Velve and Zanone et al., as applicable, is provided in paragraph no. 4 of this office action. Contrary to Applicant's assertion, Kricek et al. remedies the deficiency of Vande-Velve and Zanone et al., as applied to claims 23 and 26-29.

Claim 23 requires that the antigen mimotope be coupled to a carrier. Claims 26-27, which depend on claims 22-23, require the mimotope be conjugated to a carrier. Claims 28-29, which depend on claims 26-27, require that the mimotope be bounded to the carrier.

The significance of Vande-Velde, as applied to claims 11-12 and 21-22, is provided above. It is not readily apparent if Vande-Velde teaches mimotopes.

However, Kricek et al. teaches mimotopes and its conjugation to a carrier.

Hence, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to combine the teachings of Vande-Velde and Kricek et al. to yield a vaccine composition comprising an antigenic mimotope conjugated/bounded to a carrier and an antacid. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to avoid the antigenic degeneration of the composition of Kricek by stomach acid of the composition. One of ordinary skill in the art, at the time the invention was made, would have had a

reasonable expectation of success for doing so because the addition of antacid to vaccine compositions to avoid antigenic degeneration is routinely practiced in the art.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 11-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7348010, which was U.S. Patent Application No. 10/469162 in view of Vande-Velde and Zanone et al.

In response to the rejection, Applicant repeats Vande-Velde and Zanone et al. arguments.

Applicant's argument has been considered, however, it is not found persuasive for reason(s) discussed in paragraph no. 4 of this office action.

Claims 11-12 are directed to a vaccine composition comprising an antigen and a gastric reducing substance.

Claim 1 of the patent is directed to a composition comprising an antigen. The claim does not require that the composition comprise a gastric reducing substance.

However, Vande-Velde teaches the inclusion of a gastric reducing agent, an antacid, to avoid antigenic degeneration of an antigenic composition by stomach acid. Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include a gastric reducing substance with the composition of claim 1. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to avoid antigenic degeneration of an antigenic composition by stomach acid. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so

because the addition of antacid to compositions to avoid antigenic degeneration is routinely practiced in the art.

The antacid that Vande-Velde teaches includes aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate. It is not readily apparent from the teachings of Vande-Velde if any of the antacids disclosed in the reference acts protectively through the mucous membrane.

However, Zanone et al. teaches the use of sucralfate as an antacid, along with the other antacids disclosed by Vande-Velde, including aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate.

At the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use sucralfate as an antacid in the composition of Vande-Velde. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to make a vaccine composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of functional equivalents, one antacid for another, is routinely practiced in the art.

9. Claims 11-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 63-64 of copending Application No. 10/490920 in view of Vande-Velde and Zanone et al.

In response to the rejection, Applicant repeats Vande-Velde and Zanone et al. arguments.

Applicant's argument has been considered, however, it is not found persuasive for reason(s) discussed in paragraph no. 4 of this office action.

Claims 63-64 are directed to a composition comprising an antigen. The claim does not require that the composition comprise a gastric reducing substance.

However, Vande-Velde teaches the inclusion of a gastric reducing agent, an antacid, to avoid antigenic degeneration of an antigenic composition by stomach acid. Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include a gastric reducing substance with the vaccine composition of claims 63-64. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to avoid antigenic degeneration of an antigenic composition by stomach acid. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the addition of antacid to compositions to avoid antigenic degeneration is routinely practiced in the art.

The antacid that Vande-Velde teaches includes aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate. It is not readily apparent from the teachings of Vande-Velde if any of the antacids disclosed in the reference acts protectively through the mucous membrane.

However, Zanone et al. teaches the use of sucralfate as an antacid, along with the other antacids disclosed by Vande-Velde, including aluminium hydroxide, magnesium hydroxide, calcium carbonate, carboxylate salt, and aluminium phosphate.

At the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use sucralfate as an antacid in the composition of Vande-Velde. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to make a vaccine composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of functional equivalents, one antacid for another, is routinely practiced in the art.

This is a provisional obviousness-type double patenting rejection.

Conclusion

10. No claim is allowed.

11. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./
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